FOOD AND DRUG ADMINISTRATION
Center for Biologics Evaluation and Research (CBER)
Survey of Licensed Biologics Manufacturers and Registered Blood Establishments
for Year 2000 Compliance
SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

The Food and Drug Administration is requesting approval to survey licensed biologics manufacturers and registered blood facilities to ensure that they have addressed the Year 2000 (Y2K) problem as it affects the adequate supply of safe and effective biological products to Americans. The Y2K problem can cause a variety of errors in how dates are expressed or computed that could adversely affect automated process controls and clinical and non-clinical data integrity. If it is not addressed, non-compliant systems could adversely affect the safety and health of the American public. Manufacturers should thoroughly review and test all computer systems and have appropriate contingency plans in place before January 1, 2000.

2. How, By Whom, Purpose of Collection

Through a letter sent by the Commissioner of the Food and Drug Administration, manufacturers of biological drugs and devices, including blood and blood products will be asked to complete a survey providing a status on their Year 2000 readiness, if they have tested, verified, and certified their systems, if they have contingency plans in place, and if they use materials from foreign suppliers. FDA will ask if manufacturers intend to submit supplements to their approved applications, where applicable, so that the agency can provide appropriate staff to review the submissions in a timely manner. In addition, FDA is requesting updates on any pertinent Y2K compliance issues that might surface after completion of the attached survey. Documentation including the survey regarding the steps taken to prepare for Y2K should be available to FDA to review during inspections.

3. Consideration Given to Information Technology

Manufacturers will be able to provide responses by paper copy or facsimile. FDA intends to make public the information about a firm's state of readiness, in either a summary fashion or specific to each firm, on its website. FDA does not intend to make public specific responses from manufacturers on contingency planning or business information, but may make this information available on its website in a summary form.

4. Identification of Information

There is no similar information available that can be used or modified for use.

5. Small Businesses

FDA does not anticipate the survey will have a significant effect on small entities. The survey will request one response from manufacturers. The time for completing the survey has been estimated at 18 hours, but this is an average based on an expectation that large facilities will have many

computerized systems and a significant amount of records to review in order to be able to respond to the survey questions. We do not expect that small entities will have the same number of records, so their time to complete the survey should be less. Respondents may have been asked to provide similar information to their business partners, so will, in many instances, have the information already assembled. In addition, we are providing firms with the option of submitting the results by facsimile.

6. Less Frequent Information Collection

This information is needed to prevent any potentially serious health and safety consequences as a result of non Y2K compliant systems. Also, if suppliers to these surveyed firms do not have Y2K compliant systems, a disruption in the flow of components, packaging materials, and equipment, for example, could halt or slow the production of biological products.

7. Information Collection Circumstances

This information collection is consistent with the requirements of 5 CFR 1320.6.

8. Consultations with Persons Outside FDA

The emergency Federal Register notice that published on May 25, 1999 (64 FR 28203) provided a 7 day comment period.

9. Payment or Gift

No payment or gift will be made to respondents.

10. Confidentiality Provisions

The letter accompanying the survey instrument will inform manufacturers and facilities that a summary of the information they voluntarily provide is intended for posting on FDA's website.

11. Privacy

No questions of a sensitive nature are asked.

12. Burden of Information Collection

FDA registration and licensing databases were used to estimate the number of firms who would be subject to this collection of information. Approximately 300 licensed biologics manufacturers and 3,000 registered blood facilities will be surveyed. The estimated burden imposed on these respondents is 18 hours (per firm) to collect, prepare, and submit this information. The total estimated annual burden is 59,400 hours.

Table 1 -- Estimated Annual Reporting Burden [1]				
No. of Respondents	No. Of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours

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3,300	1	3,300	18	59,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

13. Costs to Respondents

There are no capital costs or operating and maintenance costs associated with this collection.

14. Costs to Federal Government

FDA has acquired the assistance of a contract organization to perform the tasks associated with printing, mailing and follow-up of the survey. The contractor estimates the activity will cost approximately $72,000. FDA's costs will be minimal, and are estimated to be 50 hours at $60/hour, or $3,000. FDA costs will be associated with developing mailing lists from FDA databases and working with the contractor to develop a database of survey information and refine telephone follow-up information.

15. Reason for Change

This is a new collection of information.

16. Statistical Reporting

No statistical analysis of the information is planned.

17. Display of OMB Approval Date

FDA is not seeking approval to exempt the display of the expiration date of the OMB approval.

18. Exceptions to "Certification for Paperwork Reduction Act Submissions"

There are no exceptions to certification.

B. Justification for Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Respondents: licensed biologics manufacturers and registered blood facilities. FDA registration and licensing databases were used to estimate the number of firms who would be subject to this collection of information. The estimate of the number of firms to be surveyed is 3,300 (3,000 registered blood facilities and 300 licenced biologics manufacturers).

Because of the need for information from each specific company and the very great variety of product types produced by different manufacturers, no means of sampling was identified that would produce the information required with assurance that all critical types were included in the sample.

2. Procedures for the Collection of Information

FDA will not employ statistical methods. The purpose of this survey is to obtain information on the Year 2000 readiness of licensed biologics manufacturers and registered blood facilities. The sruvey has two pricipal purposes (1) to obtain information with which to make an overall assessment of the general state of readiness of this segment of the industry and (2) to identify any manufacturer of specific, critical products whose Year 2000 readiness status could raise concerns about product availability and thus warrant agency actions to address potential shortages.

3. Methods to Maximize Response Rates and Deal With Nonresponse

FDA anticipates an initial response rate of approximately 40%, with a goal of 90-100% of all firms responding. We have contacted trade organizations and have their support in encouraging their members to complete the survey. Our plans for follow-up include a reminder and telephone contacts with each non-responding firm.

4. Test of Procedures or Methods to be Undertaken

N/A

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/orAnalyzing Data

N/A